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### TEST STRIP QUALIFICATION SYSTEM

BY

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### FIELD OF THE INVENTION

[0001] This invention relates to approaches for qualifying results obtained in using analyte test strips. The invention is particularly suited for testing the quality of test strips used for measuring prothrombin time (PT time) with whole blood in which a measurement area includes a composition that catalyzes the blood clotting cascade.

# BRIEF DESCRIPTION OF THE DRAWINGS

- Figures 1-3 represent information known in the art and are referenced in the Background of the Invention. Each of figures 44-5B diagrammatically illustrates aspects of the present invention. Variation of the invention from that shown in the figures is contemplated.
- [0003] Fig. 1A is a top view of a test strip as may be used in connection with the present invention; figure 1B is a side view of the test strip.
- [0004] Figure 2A is a schematic of hardware elements for a meter for that may be used in the present invention; figure 2B shows an alternative variation of an element of the meter of figure 2A.
- [0005] Figure 3 is a graph of data that used to determine PT time.
- [0006] Figure 4 is a graph showing a qualification zone for an assay second control.

# BACKGROUND OF THE INVENTION

[0007] European patent application EP 0 974 840 the (840 publication), published January 26, 2001, describes a device and system that may be used with the present